

25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.230

Certification of Mammography Systems
and Accreditation of Mammography Facilities

Texas Regulations for Control of Radiation

	<u>Page</u>
§289.230(a) Purpose	230-1
§289.230(b) Scope	230-1
	(revision effective February 7, 2002)
§289.230(c) Definitions	230-1
	(revision effective February 7, 2002)
§289.230(d) Prohibitions	230-10
	(revision effective February 7, 2002)
§289.230(e) Exemptions.....	230-11
	(revision effective February 7, 2002)
§289.230(f) Personnel Qualifications	230-11
	(revision effective February 7, 2002)
§289.230(g) Equipment Standards	230-18
	(revision effective February 7, 2002)
§289.230(h) Self-referral Mammography	230-21
§289.230(i) Medical Records and Mammography Reports	230-22
§289.230(j) Processing of Mammography Images	230-24
§289.230(k) Quality Assurance-General.....	230-24
	(revision effective February 7, 2002)
§289.230(l) Quality Assurance-Equipment	230-25
	(revision effective February 7, 2002)
§289.230(m) Quality Assurance-Mammography Medical Outcomes Audit	230-36
§289.230(n) Mammographic Procedure and Techniques for Mammography of Patients with Breast Implants	230-37
§289.230(o) Clinical Image Quality	230-37
§289.230(p) Medical Research	230-37
	(revision effective February 7, 2002)
§289.230(q) Requirements for Mammography Systems Used Exclusively for Invasive Interventions for Localizations or Biopsy Procedures	230-37
	(revision effective February 7, 2002)
§289.230(r) Record Requirements	230-39
	(revision effective February 7, 2002)

25 TAC §289.230

**Certification of Mammography Systems
and Accreditation of Mammography Facilities (Continued)**

	<u>Page</u>
§289.230(s) Other Operating Procedures	230-41
(revision effective February 7, 2002)	
§289.230(t) Certification Requirements (state certification)	230-42
(revision effective February 7, 2002)	
§289.230(u) Issuance of Certification of Mammography Systems	230-44
(revision effective February 7, 2002)	
§289.230(v) Specific Terms and Conditions of Certification of Mammography Systems	230-44
§289.230(w) Responsibilities of Registrant	230-45
(revision effective February 7, 2002)	
§289.230(x) Expiration of Certification of Mammography Systems	230-47
§289.230(y) Termination of Certification of Mammography Systems ...	230-47
§289.230(z) Renewal of Certification of Mammography Systems	230-47
(revision effective February 7, 2002)	
§289.230(aa) Modification and Revocation of Certification of Mammography Systems	230-48
(revision effective February 7, 2002)	
§289.230(bb) Reciprocal Recognition of Out-Of-State Certificates of Registration	230-48
§289.230(cc) Inspections	230-48
(revision effective February 7, 2002)	
§289.230(dd) Accreditation of Mammography Facilities	230-50
(revision effective February 7, 2002)	
§289.230(ee) Fees for Accreditation of Mammography Facilities	230-51
(revision effective February 7, 2002)	
§289.230(ff) Issuance of Accreditation of a Mammography Facility	230-52
(revision effective February 7, 2002)	
§289.230(gg) Specific Terms and Conditions of Accreditation of Mammography Facilities	230-52
§289.230(hh) Responsibilities of an Accredited Facility	230-53
§289.230(ii) Expiration and Renewal of Accreditation of Mammography Facilities	230-53
(revision effective February 7, 2002)	
§289.230(jj) Denial or Abandonment of an Application for Accreditation of Mammography Facilities	230-53
(revision effective February 7, 2002)	

25 TAC §289.230

**Certification of Mammography Systems
and Accreditation of Mammography Facilities (Continued)**

		<u>Page</u>
§289.230(kk)	Revocation and Suspension of Accreditation of Mammography Facilities	230-54
	(revision effective February 7, 2002)	
§289.230(ll)	On-site Facility Visit, Targeted Clinical Image Review, and Random Film Checks	230-55
	(revision effective February 7, 2002)	
§289.230(mm)	Complaints	230-56
	(revision effective February 7, 2002)	
§289.230(nn)	Appendices	230-56
§289.230(nn)(1)	Subjects to be Included in Mammography Training for Medical Radiologic Technologists	230-56
§289.230(nn)(2)	Subjects to be Included in Mammography Training for Interpreting Physicians	230-57
§289.230(nn)(3)	Time Requirements for Record Keeping	230-57
	(revision effective February 7, 2002)	
§289.230(nn)(4)	Operating and Safety Procedures	230-59
	(revision effective February 7, 2002)	
§289.230(nn)(5)	Phantom Image Scoring Protocol	230-60
<u>Miscellaneous</u>	Texas Register Format Explanation Where Can the Forms Referenced Within the Rule Be Found?	

25 TEXAS ADMINISTRATIVE CODE

§289.230. Certification of Mammography Systems and Accreditation of Mammography Facilities.

(a) Purpose.

(1) This section provides for the certification of mammography systems and the accreditation of mammography facilities. No person shall use x-ray producing machines for mammography of humans except as authorized in a state certification of mammography systems issued by the agency in accordance with the requirements of this section and in a certificate issued by the United States Food and Drug Administration (FDA).

(2) The use of all mammography machines certified in accordance with this section shall be by or under the supervision of a physician licensed by the Texas State Board of Medical Examiners.

(b) Scope. In addition to the requirements of this section, all registrants are subject to the requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title (relating to Registration of Radiation Machine Use and Services), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation). This section does not apply to an entity under the jurisdiction of the federal government.

(c) Definitions. The following words and terms, when used in this section, shall have the following meaning unless the context clearly indicates otherwise.

(1) Accreditation - An approval of a mammography facility by an accreditation body.

(2) Accreditation body - An entity approved by the FDA under Title 21, Code of Federal Regulations (CFR), Part 900.3(d) to accredit mammography facilities.

(3) Action limit - The minimum or maximum value of a quality assurance measurement representing acceptable performance. Values less than the minimum or greater than the maximum action limit indicate that corrective action must be taken by the facility.

(4) Additional mammography review - At the request of the FDA or an accreditation body, a review by the accreditation body of clinical images and other relevant facility information necessary to assess conformation with the accreditation standards. The reviews include the following:

(A) additional mammography review with interpretation; or

(B) additional mammography review without interpretation.

(5) Adverse event - An undesirable experience associated with mammography activities within the scope of this section. Adverse events include but are not limited to:

(A) poor image quality;

(B) failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

(C) use of personnel who do not meet the applicable requirements of subsection (f) of this section.

(6) Air kerma - The kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.

(7) Automatic exposure control (AEC) - A device that automatically controls one or more technique factors in order to obtain at preselected locations a required quantity of radiation.

(8) Average glandular dose - The value in millirad (mrad) or milligray (mGy) for a given breast or phantom thickness that estimates the average absorbed dose to the glandular tissue extrapolated from free air exposures and based on fixed filter thickness and target material.

(9) Backup processor - A processor used to develop mammograms when the processor commonly in use for mammography is out of service.

(10) Beam-limiting device - A device that provides a means to restrict the dimensions of the x-ray field.

(11) Breast implant - A prosthetic device implanted in the breast.

(12) Calendar quarter - Any one of the following time periods during a given year: January 1-March 31, April 1-June 30, July 1-September 30, or October 1-December 31.

(13) Calibration of instruments - The comparative response or reading of an instrument relative to a series of known radiation values over the range of the instrument.

(14) Category I continuing medical education units (CMEU) - Educational activities designated as Category I and approved by the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, a state medical society, or an equivalent organization.

(15) Certification of mammography systems (state certification) - A form of permission given by the agency to an applicant who has met the requirements for mammography system certification set out in the Texas Radiation Control Act, Health and Safety Code, Chapter 401 (Act) and this chapter.

(16) Clinical image - See the definition for mammogram.

(17) Consumer - An individual who chooses to comment or complain in reference to a mammography examination. The individual may be the patient or a representative of the patient, such as a family member or referring physician.

(18) Contact hour - An hour of training received through direct instruction.

(19) Continuing education unit (CEU) - One contact hour of training.

(20) Control panel - That part of the radiation machine control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

(21) Dedicated mammographic equipment - Equipment that has been specifically designed and manufactured for mammography.

(22) Direct instruction - Instruction that includes:

(A) face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(B) the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(23) Direct supervision - Oversight of operations that include the following.

(A) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's record.

(B) During performance of a mammography examination, the supervising medical radiologic technologist is present to observe and correct, as needed, the individual who is performing the examination.

(C) During performance of a survey of the registrant's equipment and quality assurance program, the supervising medical physicist is present to observe, and correct, as needed, the individual who is conducting the survey.

(24) Established operating level - The value of a particular quality assurance parameter that has been established as an acceptable normal level by the registrant's quality assurance program.

(25) Facility - A hospital, outpatient department, clinic, radiology practice, mobile unit, an office of a physician, or other person that conducts breast cancer screening or diagnosis through mammography activities, including any or all of the following:

- (A) the operation of equipment to produce a mammogram;
- (B) processing of film;
- (C) initial interpretation of the mammogram; or
- (D) maintaining the viewing conditions for that interpretation.

(26) Final assessment categories - The overall final assessment of findings in a report of a mammography examination, classified in one of the following categories:

(A) "negative" indicates nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

(B) "benign" is also a negative assessment;

(C) "probably benign" indicates a finding(s) that has a high probability of being benign;

(D) "suspicious" indicates a finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) "highly suggestive of malignancy" indicates a finding(s) that has a high probability of being malignant; or

(F) "incomplete" indicates there is a need for additional imaging evaluation. Reasons why no assessment can be made shall be stated by the interpreting physician.

(27) First allowable time - The earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

(28) Formal training - Attendance and participation in direct instruction. This does not include self-study programs.

(29) Half-value layer (HVL) - The thickness of a specified material that attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any that might be present initially in the beam concerned, is deemed to be excluded.

(30) Healing arts - Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(31) Image receptor - Any device, such as a fluorescent screen or radiographic film, that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

(32) Image review board - A group of qualified review physicians and other individuals who review the clinical and phantom images and whose qualifications have been established by the accreditation body and the accreditation body's qualifications have been approved by the FDA.

(33) Institutional review board (IRB) - Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(34) Interpreting physician - A licensed physician who interprets mammographic images and who meets the requirements of subsection (f)(1) of this section.

(35) Kerma - The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(36) Laterality - The designation of either the right or left breast.

(37) Lead interpreting physician - The interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of subsections (k), (l), and (m) of this section.

(38) Mammogram - A radiographic image produced through mammography.

(39) Mammography - The use of x-radiation to produce an image of the breast that may be used to detect the presence of pathological conditions of the breast. For the purposes of this section, mammography does not include radiography of the breast performed as follows:

(A) during invasive interventions for localization or biopsy procedures except as specified in subsection (q) of this section; or

(B) with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations.

(40) Mammographic modality - A technology for radiography of the breast. Examples are screen-film mammography and full-field digital mammography.

(41) Mammography medical outcomes audit - A systematic collection of mammography results compared with outcomes data.

(42) Mammography system - A system that includes the following:

(A) an x-ray machine used as a source of radiation in producing images of breast tissue;

(B) an imaging system used for the formation of a latent image of breast tissue;

(C) an imaging processing device for changing a latent image of breast tissue to a visual image that can be used for diagnostic purposes;

(D) a viewing device used for the visual evaluation of an image of breast tissue if the image is produced in interpreting visual data captured on an image receptor;

(E) a medical radiologic technologist who performs mammography; and

(F) a physician who engages in, and who meets the requirements of this section relating to the reading, evaluation, and interpretation of mammograms.

(43) Mammography machine(s) - A unit consisting of components assembled for the production of x-rays for use during mammography. These include, at a minimum, the following:

- (A) an x-ray generator;
- (B) an x-ray control;
- (C) a tube housing assembly;
- (D) a beam limiting device; and
- (E) supporting structures.

(44) Mean optical density - The average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters (cm) with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

(45) Medical physicist - An individual who performs surveys and evaluations of mammographic equipment in accordance with this section and who meets the qualifications in subsection (f)(3) of this section.

(46) Medical radiologic technologist (operator of equipment) - An individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations, who performs mammography examinations in accordance with this section and who meets the qualifications in subsection (f)(2) of this section.

(47) Mobile services - The use of mammography machines in temporary locations for limited time periods. The mammography machines may be fixed inside a mobile van or transported to temporary locations.

(48) Multi-reading - Two or more physicians interpreting the same mammogram. At least one physician shall be qualified as an interpreting physician.

(49) Optical density (OD) - A measure of the fraction of incident light transmitted through a developed film and defined by the equation:

$$OD = \log_{10} \frac{I_o}{I_t}$$

where I_o = light intensity incident on the film and
 I_t = light transmitted through the film.

(50) Patient - Any individual who undergoes a mammography examination in a facility, regardless of whether the person is referred by a physician or is self-referred.

(51) Phantom - A test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. The phantom shall be accepted by FDA.

(52) Phantom image - A radiographic image of a phantom.

(53) Physical science - This includes physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(54) Positive mammogram - A mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

(55) Qualified instructor - An individual whose training and experience prepares him or her to carry out specified training assignments. Interpreting physicians, medical radiologic technologists, or medical physicists who meet the requirements of subsection (f) of this section would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the requirements of this section include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

(56) Quality control technologist - An individual meeting the requirements of subsection (f)(2) of this section who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(57) Radiation machine - For the purposes of this part, radiation machine also means unit.

(58) Reinstatement fee - The fee charged to reinstate an application for a mammography machine that has been denied accreditation or whose application has been abandoned in accordance with subsection (jj) of this section.

(59) Review physician - An individual who is qualified to review clinical images on behalf of the accreditation body. To be qualified, this individual shall comply with the following:

(A) meet the interpreting physician requirements of subsection (f)(1) of this section;

(B) be trained and evaluated in the clinical image review process for the types of clinical images to be evaluated by a review physician by the accreditation body before designation as a review physician and periodically thereafter; and

(C) clearly document their findings and reasons for assigning a particular score to any clinical image and provide information to the facility for use in improving the attributes for which significant deficiencies were identified.

(60) Self-referral mammography - The use of x-radiation to test asymptomatic women for the detection of diseases of the breasts when such tests are not specifically and individually ordered by a licensed physician.

(61) Serious adverse event - An adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(62) Serious complaint - A report of a serious adverse event.

(63) Source-to-image receptor distance (SID) - The distance from the source to the center of the input surface of the image receptor.

(64) Standard breast - A 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue.

(65) Survey - An on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

(66) Targeted clinical image review - A review of two sets of "negative" clinical images from a specific date at the request of the agency. The review is performed due to a serious complaint or a severe item of non-compliance.

(67) Technique chart - A chart that provides all necessary generator control settings and geometry needed to make clinical radiographs.

(68) Traceable to a national standard - Calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years. The results of the proficiency test conducted within 24 months of calibration shall show agreement within plus or minus 3.0% of the national standard in the mammography energy range.

(d) Prohibitions.

(1) Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This includes systems that have been modified or equipped with special attachments for mammography.

(2) The agency may prohibit use of mammography machines that pose a significant threat or endanger public health and safety, in accordance with §289.231 of this title and §289.205 of this title.

(3) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed physician. This provision specifically prohibits deliberate exposure for the following purposes:

(A) exposure of an individual for training, demonstration, or other non-healing arts purposes;

(B) exposure of an individual for the purpose of healing arts screening (self referral mammography) except as authorized by subsection (h) of this section; and

(C) exposure of an individual for the purpose of research except as authorized by subsection (p) of this section.

(e) Exemptions.

(1) Mammography machines or cabinet x-ray machines used exclusively for examination of breast biopsy specimens are exempt from the requirements of this section. These machines are required to meet applicable provisions of §289.226 of this title and §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts and Veterinary Medicine).

(2) Xerography systems not used for detection of diseases of the breast are exempt from the requirements of this section. These machines are required to meet applicable provisions of §289.226 of this title and §289.227 of this title.

(3) Mammography systems used exclusively for invasive interventions for localization or biopsy procedures are exempt from the requirements of this section except for those listed in subsection (q) of this section.

(4) Mammography systems used exclusively for research or investigation are exempt from the requirements of this section.

(5) All mammography registrants are exempt from the posting of radiation area requirements of §289.231(x) of this title provided that the operator has continuous surveillance and access control of the radiation area.

(f) Personnel qualifications. The following requirements apply to all personnel involved in any aspect of mammography including the production and interpretation of mammograms.

(1) Interpreting physician. Each physician interpreting mammograms shall hold a current Texas license issued by the Texas State Board of Medical Examiners and meet the following qualifications.

(A) Initial qualifications. Before interpreting mammograms independently, the physician shall:

(i) be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or one of the other bodies approved by the FDA to certify interpreting physicians or have at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography in accordance with subsection (nn)(2) of this section;

(ii) have had 60 hours of documented category I CMEUs in mammography. At least 15 of the 60 hours shall have been acquired within three years immediately prior to the date that the physician qualified as an interpreting physician. Hours spent in residency specifically devoted to mammography will be equivalent to category I CMEUs and accepted if documented in writing by the appropriate representative of the training institution. The residency program must be approved by the Accreditation Council for Graduate Medical Education or the Council on Postdoctoral Training of the American Osteopathic Association; and

(iii) have interpreted or multi-read, under the direct supervision of an interpreting physician, at least 240 mammographic examinations within the six month period immediately prior to the date that the physician qualifies as an interpreting physician.

(B) Exemptions.

(i) Physicians who qualified as interpreting physicians in accordance with the requirements of §289.230 that were in effect prior to April 28, 1999, or any other equivalent state or federal requirements in effect prior to April 28, 1999, are considered to have met the initial requirements of subparagraph (A) of this paragraph.

(ii) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six month period during the last two years of a diagnostic radiology residency and who became board certified at the first allowable time, are exempt from subparagraph (A)(iii) of this paragraph.

(C) Continuing education and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. These periods begin when a physician completes the requirements to become an interpreting physician in subparagraph (A) of this paragraph. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each interpreting physician shall maintain qualifications by meeting the following requirements:

(i) participating in education programs by completing at least 15 category I CMEUs in mammography that shall include at least six CMEUs in each modality used by the interpreting physician in his/her practice or by teaching mammography courses. CMEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:

§289.230(f)(1)(C)(i)(I)

(I) the date of the registrant's annual inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two;

(ii) interpreting or multi-reading at least 960 mammographic examinations that must be completed during the 24 months immediately preceding:

(I) the date of the registrant's annual inspection; or

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two; and

(iii) accumulating at least eight hours of CMEUs in any mammography modality in which the interpreting physician has not been previously trained, prior to independently using the new modality.

(D) Re-establishing qualifications. Before resuming independent interpretation of mammograms, interpreting physicians who fail to maintain the required continuing education or experience requirements shall re-establish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtain a sufficient number of additional category I CMEUs to bring their total up to the 15 category I CMEU credits required in the previous 36 months; and

(ii) within the six months immediately prior to resuming independent interpretation and under the direct supervision of an interpreting physician, interpret or multi-read one of the following, whichever is less:

(I) at least 240 mammographic examinations; or

(II) a sufficient number of mammographic examinations to bring the total up to 960 examinations for the prior 24 months.

(2) Medical radiologic technologists (operators of equipment). Each person performing mammographic examinations shall have current certification as a medical radiologic technologist under the **Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601** and shall meet the following qualifications.

(A) Initial requirements. Before performing mammographic examinations, the operator of equipment shall have:

(i) completed a minimum of 40 contact hours of training as outlined in subsection (nn)(1) of this section by a qualified instructor; and

(ii) performed a minimum of 25 mammographic examinations under the direct supervision of an individual qualified in accordance with the qualifications of this paragraph. The 25 mammographic examinations may be obtained concurrently with the 40 contact hours of training specified in clause (i) of this subparagraph but shall not exceed 16 hours of the 40 contact hours.

(B) Exemptions. Equipment operators who qualified as medical radiologic technologists to perform mammography in accordance with the requirements of §289.230 that were in effect prior to April 28, 1999, or any other equivalent state or federal requirements in effect prior to April 28, 1999, are considered to have met the initial requirements of subparagraph (A) of this paragraph.

(C) Continuing education and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. The period for continuing education begins when a technologist completes the requirements in subparagraph (A) of this paragraph. The period for continuing experience begins when a technologist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each medical radiologic technologist shall maintain qualifications by meeting the following requirements:

(i) participating in education programs by completing at least 15 CEUs in mammography that shall include at least six CEUs in each modality used by the technologist or by teaching mammography courses. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:

(i) the date of the registrant's annual inspection;

§289.230(f)(2)(C)(i)(II)

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two;

(ii) performing a minimum of 200 mammographic examinations that must be completed during the 24 months immediately preceding:

(I) the facility's annual inspection;

(II) the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two; and

(iii) accumulating at least eight hours of CEUs in any mammography modality in which the medical radiologic technologist has not been previously trained, prior to independently using the new modality.

(D) Requalification. Before resuming independent performance of mammograms, medical radiologic technologists who fail to maintain the continuing education or experience requirements shall re-establish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtaining a sufficient number of additional CEUs to bring their total up to the 15 CEU credits required in the previous 36 months;

(ii) performing a minimum of 25 mammographic examinations under the direct supervision of a qualified medical radiologic technologist.

(3) Medical physicist. Each medical physicist performing mammographic surveys and evaluating mammographic equipment shall hold a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in diagnostic radiological physics and be registered with the agency or employed by a business registered with the agency, in accordance with §289.226(e) of this title and the Act, unless exempted by §289.226(d)(6) of this title. Each medical physicist shall meet the following qualifications:

(A) Initial qualifications. Before performing surveys and evaluating mammographic equipment independently, the medical physicist shall:

(i) have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (30 quarter hours) of college undergraduate or graduate level physics;

(ii) have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) have experience conducting surveys of at least one mammography facility and a total of at least ten mammography machines. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets the requirements of subparagraphs (A) and (C) of this paragraph. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement; or

(B) Alternative initial qualifications. Individuals who qualified as a medical physicist in accordance with the requirements of §289.230 that were in effect prior to April 28, 1999, or any other equivalent state or federal requirements in effect prior to April 28, 1999, and have met the following additional qualifications prior to April 28, 1999, are determined to have met the initial qualifications of subparagraph (A) of this paragraph:

(i) a bachelor's degree or higher in a physical science from an accredited institution with no less than ten semester hours or equivalent of college undergraduate or graduate level physics;

(ii) 40 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) experience conducting surveys of at least one mammography facility and a total of at least 20 mammography machines. No more than one survey of a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement. The training and experience requirements must be met after fulfilling the degree requirements.

(C) Continuing education and experience. The time period for completing continuing education is a 36-month period and the time period for completing continuing experience is a 24-month period. The period for continuing education will begin when a physicist completes the requirements in subparagraph (A) of this paragraph. The time period for continuing experience will begin when a physicist completes the requirements in subparagraph (A) of this paragraph, or April 28, 1999, whichever is later. The facility shall choose one of the dates in clause (i) of this subparagraph to determine the 36-month continuing education period and one of the dates in clause (ii) of this subparagraph to determine the 24-month continuing experience period. Each medical physicist shall maintain their qualifications by meeting the following requirements:

§289.230(f)(3)(C)(i)

(i) participating in education programs, either by teaching or completing at least 15 CEUs in mammography that shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys. CEUs earned through teaching a specific course can be counted only once during the 36-month period. The continuing education must be completed in the 36 months immediately preceding:

(I) the date of the registrant's annual inspection;

(II) by the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two;

(ii) performing surveys of two mammography facilities and a total of at least six mammography machines (no more than one survey of a specific facility within a ten-month period or a specific machine within a period of 60 days can be counted towards the total mammography machine survey requirement). The continuing experience must be completed during the 24 months immediately preceding:

(I) the date of the facility's annual inspection;

(II) by the last day of the calendar quarter preceding the inspection; or

(III) any date in between the two; and

(iii) accumulating at least eight hours of CEUs in any mammography modality in which the medical physicist has not been previously trained, prior to independently using the new modality.

(D) Re-establishing qualifications. Before resuming independent performance of surveys and equipment evaluations, medical physicists who fail to maintain the continuing education or experience requirements shall reestablish their qualifications by completing one or both of the following requirements, as applicable:

(i) obtaining a sufficient number of additional CEUs to bring their total up to the 15 CEU credits required in the previous 36 months; and

(ii) performing a sufficient number of surveys, under the direct supervision of a qualified medical physicist, to bring their total up to two mammography facilities and a total of at least six mammography units for the prior 24 months.

(4) Retention of personnel records. Records documenting the qualifications, continuing education, and experience of personnel in subsection (f)(1)-(3) shall be maintained for inspection by the agency in accordance with subsection (nn)(3) of this section.

(g) Equipment standards. Only x-ray systems meeting the following standards shall be used.

(1) System design. The equipment shall have been specifically designed and manufactured for mammography and in accordance with Title 21, CFR, §§ 1010.2, 1020.30, and 1020.31.

(2) Motion of tube-image receptor assembly. The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. In the event of power interruption, this mechanism shall not fail.

(3) Image receptor sizes. Systems using screen-film image receptors shall, at a minimum, provide for the following:

(A) operation with image receptors of 18 x 24 cm and 24 x 30 cm;

(B) operable moving grids matched to all image receptor sizes provided;

(C) operation with the grid removed for systems used for magnification procedures; and

(D) image receptors to rest, post-loading, 15 minutes between exposures.

(4) Magnification. Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use with, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

(5) Focal spot and target material selection. Selection of the focal spot or target material shall be as follows.

§289.230(g)(5)(A)

(A) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(B) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(C) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

(6) Compression. All mammography systems shall incorporate a compression device.

(A) Application of compression. Effective October 28, 2002, and thereafter, each system shall provide the following features operable from both sides of the patient:

(i) an initial power-driven compression activated by hands-free controls; and

(ii) fine adjustment compression controls.

(B) Compression paddle.

(i) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.

(ii) Compression paddles for special purposes, including those smaller than the full size of the image receptor (spot compression) may be provided. Such paddles are not subject to the requirements of clauses (v) and (vi) of this subparagraph.

(iii) Except as provided in clause (iv) of this subparagraph, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(iv) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(v) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(vj) The chest wall edge may be bent upward to allow for patient comfort, but shall not appear on the image.

(7) Technique factor selection and display. Technique factor selection and display shall be as follows.

(A) Manual selection of milliamperere seconds (mAs) or at least one of its component parts, milliamperere (mA) and/or time, shall be available.

(B) The technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(C) When the AEC mode is used, the system shall indicate the actual kVp and mAs used during the exposure. The mAs may be displayed as mA and time.

(8) Automatic exposure control. Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, for example, grid, nongrid, magnification, non magnification, and various target filter combinations.

(A) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(i) The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

(ii) The selected position of the detector shall be clearly indicated.

(B) The system shall provide means to vary the selected optical density from the normal (zero) setting.

(9) X-ray film. The registrant shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(10) Intensifying screens. The registrant shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

(11) Film processing solutions. For processing mammography films, the registrant shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(12) Lighting. The registrant shall make available special lights for film illumination (hot lights) capable of producing light levels greater than that provided by the view box.

(13) Film masking devices. Registrants shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

(14) Equipment variances. Registrants with mammography equipment that has been issued variances by FDA to Title 21, CFR, §§1020.2, 1020.30, 1020.31 or has had an alternative for a quality standard for equipment approved by the FDA under the provisions of Title 21, CFR, §900.18, shall maintain copies of those variances or alternative standards.

(h) Self-referral mammography. Any person proposing to conduct a self-referral mammography program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the following information:

- (1) the number and type of views (or projections);
- (2) the age of the population to be examined and the frequency of the exam following established, nationally recognized criteria, such as those of the American Cancer Society, American College of Radiology (ACR), or the National Council on Radiation Protection and Measurements;
- (3) written procedures to include methods of:
 - (A) advising patients and private physicians of the results of the mammography examination in accordance with subsection (i)(2) of this section;
 - (B) follow-up with patients and physicians in accordance with subsection (i)(3) of this section; and

(C) recommending to patients who do not have a physician means of selecting a physician;

(4) methods for educating mammography patients in breast self-examination techniques and on the necessity for follow-up by a physician.

(i) Medical records and mammography reports.

(1) Contents and terminology. Each registrant shall prepare a written report of the results of each mammography examination that shall include the following information:

(A) name of the patient and an additional patient identifier;

(B) date of the examination;

(C) name and signature of the interpreting physician who interpreted the mammogram (electronic signatures are acceptable);

(D) overall final assessment of findings using the final assessment categories as defined in subsection (c) of this section; and

(E) recommendations made to the practitioner about what additional actions, if any, should be taken. All clinical questions raised by the referring physician shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(2) Communication of mammography results to the patient and physicians. Each registrant shall send reports as soon as possible, but no later than 30 days from the date of the mammography examination to:

(A) patients advising them of the results of the mammography examination and any further medical needs indicated. The report shall include a summary written in language easily understood by a lay person; and

(B) referring physicians, or in the case of self-referral, to the physician indicated by the patient, advising them of the results of the mammography examination, containing the information specified in paragraph (1) of this subsection, and any further medical needs indicated.

(3) Follow-up with patients and physicians. Each registrant shall follow-up to confirm the following:

§289.230(i)(3)(A)

(A) that patients with positive findings and patients needing repeat exams have received proper notification; and

(B) that physicians have received proper notification of patients with positive findings needing repeat exams.

(4) Retention of clinical images. Each registrant that performs mammograms shall do the following.

(A) Maintain mammography films and reports in a permanent medical record for a minimum of five years and if no additional mammograms of the patient are performed at the facility, they shall be maintained for a minimum of ten years.

(B) Upon request or on behalf of the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician, or to the patient directly.

(C) If the medical records are permanently forwarded, the receiving institution or physician shall maintain and become responsible for the original film until the fifth or tenth anniversary, as specified in subparagraph (A) of this paragraph unless permanently transferred or forwarded in accordance with subparagraph (B) of this paragraph.

(5) Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible manner and placed so as not to obscure anatomic structures:

(A) name of patient and an additional patient identifier;

(B) date of examination;

(C) view and laterality (this information shall be placed on the image in a position near the axilla);

(D) facility name and location (at a minimum the location shall include city, state, and zip code);

(E) technologist identification;

(F) cassette/screen identification; and

(G) mammography machine identification if there is more than one machine in the facility.

§289.230(i)(6)

(6) Information shall also be maintained for each clinical image by utilizing a label on each film, recording on the film jacket, or maintaining a log or other means. The information shall include, but is not limited to, compressed breast thickness or degree of compression, and kVp.

(j) Processing of mammographic images. Each registrant shall utilize the same processor for clinical and phantom images. Clinical images shall be processed within an interval not to exceed 24 hours from the time the first clinical image is taken. Facilities utilizing batch processing shall:

(1) use a container to transport clinical images that will protect the film from exposure to light and radiation; and

(2) maintain a log to include each patient name and unique identification number, date, and time of the first exam of each batch, and date and time of batch development.

(k) Quality assurance - general. Each registrant shall establish and maintain a written quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the mammography facility, including corrective actions to be taken if images are of poor quality.

(1) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(A) Lead interpreting physician. The registrant shall identify a lead interpreting physician who shall have the general responsibility of:

(i) ensuring that the quality assurance program meets all requirements of this subsection and subsections (l) and (m) of this section;

(ii) reviewing and documenting the technologists' quality control test results at least every three months or more frequently if consistency has not yet been achieved;

(iii) reviewing the physicists' results annually or more frequently when needed; and

(iv) assigning and determining the individual's qualifications to perform the quality assurance tasks in subparagraphs (B)-(D) of this paragraph.

(B) Interpreting physicians. All interpreting physicians interpreting mammograms for the registrant shall:

(i) follow the registrant's procedures for corrective action when the images they are asked to interpret are of poor quality. These procedures shall be included in the facility's operating and safety procedures; and

(ii) participate in the medical outcomes audit program.

(C) Medical physicist. Each registrant shall use the services of a licensed medical physicist to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist shall be responsible for performing the surveys and the mammography equipment evaluations and providing the facility with the reports described in subsection (l)(10) and (11) of this section.

(D) Quality control technologist. The quality control technologist, designated by the lead interpreting physician, shall ensure performance of the items designated in subsection (l)(1)-(4), (7), (9), (12), and (14) of this section. If other personnel are assigned the quality assurance tasks in accordance with subparagraph (A)(iv) of this paragraph, the quality assurance technologist shall insure that the requirements of subsection (l)(1)-(4), (7), (9), (12), and (14) of this section are met.

(2) Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (include monitoring data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. These quality control records shall be kept for each test specified in subsection (l) and (m) of this section, in accordance with subsection (nn)(3) of this section.

(l) Quality assurance - equipment. Registrants with screen-film systems shall perform the following quality control tests at the intervals specified. In addition to the intervals specified in (l)(4)(B) and (5)(H), the tests shall be performed prior to initial use.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be completed and the results charted on each day that clinical films are processed before any clinical films are processed that day.

(A) Processor performance test. Using mammography film used clinically at the facility, sensitometer tests shall include assessment of the following:

(i) base plus fog density that shall be within plus 0.03 of the established operating level;

(ii) mid-density that shall be within plus or minus 0.15 of the established operating level; and

(iii) density difference that shall be within plus or minus 0.15 of the established operating level.

(B) Backup processor. A processor, other than the one commonly in use for mammography, may be designated as a backup processor that may be used temporarily. To be designated as a backup processor, the processor shall be tested and meet the requirements of subparagraph (A) of this paragraph for a minimum of five days to establish operating levels. The backup processor shall meet the requirements of subparagraph (A) of this paragraph at all times during use for developing patient mammograms. Prior to the first patient exposure of each period of use, a phantom image shall be acquired, developed in the backup processor, and shall meet the requirements of paragraph (2) of this section.

(C) Film processors being used for mammography at multiple locations, such as a mobile service, shall be subject to the requirements of this paragraph.

(D) Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

(2) Weekly quality control tests. These tests shall be performed at an interval no greater than seven days. If mammography is not being performed on the date the test is due and more than seven days have past since the last test, the tests shall be performed prior to resuming mammography. An image quality evaluation test, using an FDA-accepted phantom, shall meet the following parameters.

(A) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition and shall not change by more than plus or minus 0.20 from the established operating level.

(B) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(C) The phantom image shall be made on the standard mammographic film in use at the facility with techniques used for clinical images of a standard breast. The phantom image shall meet the requirements in subparagraphs (A) and (B) of this paragraph and clause (j) of this subparagraph. No mammograms shall be taken on patients if any of these minimums are not met.

(j) The mammographic machine shall be capable of producing images of the mammographic phantom in accordance with the phantom image scoring protocol in subsection (nn)(5) of this section.

(ii) Each phantom image and a record of the evaluation of that image shall be maintained at the location where the mammography image was produced or with the radiographic equipment for mobile services.

(3) Quarterly quality control tests. These tests shall be performed within the calendar quarter at an interval not to exceed 90 days.

(A) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(B) Repeat analysis. A repeat analysis on clinical images repeated or rejected shall be performed, analyzed, and documented. The total repeat or reject rate shall not exceed 5.0%. If the total repeat or reject rate changes from the previously determined rate by more than 2.0% of the total films included in the analysis, the reason(s) for the change shall be determined. Corrective action shall be taken and documented if the total repeat or reject rate for the facility exceeds 5.0% or changes from the previously determined rate by more than 2.0% of the total films included in the analysis. Test films, cleared films, or film processed as a result of exposure of a film bin are not to be included in the count for repeat analysis. Films included in the repeat analysis are not required to be kept after completion of the analysis.

(4) Semiannual quality control tests. **These tests shall be performed at an interval not to exceed six months.**

(A) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the counter top, emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(B) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. The entire area of the cassette that may be clinically exposed shall be tested. This shall include all cassettes used for mammography in the facility.

(C) Compression device performance. The x-ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least 15 seconds. Effective October 28, 2002, and thereafter, the maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds.

(5) Annual quality control tests. These tests shall be performed at an interval not to exceed 12 months.

(A) Automatic exposure control performance. The AEC shall be as follows.

(i) The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

(ii) Effective October 28, 2002, and thereafter, the AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(iii) The optical density of the film in the center of the phantom image shall not be less than 1.20.

(B) Kilovoltage peak accuracy and reproducibility. At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be accurate to within plus or minus 5.0% of the indicated or selected kVp at the following:

(i) the lowest clinical kVp that can be measured by a kVp test device;

(ii) the most commonly used clinical kVp; and

(iii) the highest available clinical kVp.

(C) Focal spot condition. **Until October 27, 2002,** focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. **Effective October 28, 2002, and thereafter, facilities shall evaluate focal spot condition only by determining the system resolution.**

(i) System resolution.

(I) Each x-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(II) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(III) When more than one target material is provided, the measurement in subclause (I) of this clause shall be made using the appropriate focal spot for each target material.

(IV) When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.

(V) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(ii) Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified as follows.

TABLE I

Focal Spot Tolerance Limit

Maximum Measured Dimensions

<u>Nominal Focal Spot Size (mm)</u>	<u>Width (mm)</u>	<u>Length (mm)</u>
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

(D) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Title 21, CFR, §1020.30(m)(1) for the minimum HVL. These values, extrapolated to the mammographic range, are shown as follows. Values not shown in Table II may be determined by linear interpolation or extrapolation.

TABLE II

X-ray Tube Voltage (kilovolt peak) and Minimum HVL

Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (mm of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

(E) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

(F) Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure.

(G) X-ray field/light field/image receptor/compression paddle alignment. All systems shall meet the following:

(i) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2.0% of the SID.

(ii) If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2.0% of the SID.

(iii) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1.0% of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(H) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(I) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

(J) Radiation output. The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography (molybdenum/molybdenum) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. Effective October 28, 2002, and thereafter, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 milliroentgen (mR) per second). The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(K) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides the following:

- (i) an override capability to allow maintenance of compression;
- (ii) a continuous display of the override status; and
- (iii) a manual emergency compression release that can be activated in the event of power or automatic release failure.

(L) The technique settings used for subparagraphs (D) and (F) of this paragraph and paragraph (2) of this subsection shall be those used by the facility for its clinical images of a standard breast.

(6) Densitometer and sensitometer. The calibration of the densitometer and sensitometer must be in accordance with the manufacturer's specifications.

(7) Quality control tests--other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (5)(F) of this subsection.

(8) Mobile **mammography machines**. The registrant shall verify that **mammography machines** used to produce mammograms at more than one location meet the requirements in paragraphs (1)-(7) of this subsection. In addition, at each examination location, before any examinations are conducted, the registrant shall verify satisfactory performance of the **mammography machines** by using a test method that establishes the adequacy of the image quality produced by the machine. Processor performance shall be in accordance with paragraph (1) of this subsection.

(9) Use of test results. After completion of the tests specified in paragraphs (1)-(8) of this subsection, the registrant shall do the following.

(A) Compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or for post-move, pre-examination testing of mobile **mammography machines**, to the limits established in the test method used by the facility.

(B) Components of the mammography system that fail any of the following quality assurance tests shall comply with the actions in subparagraph (C) of this paragraph:

(i) paragraph (1) of this subsection describing processor quality control;

(ii) paragraph (2) of this subsection describing phantom image quality;

(iii) paragraph (4)(A) of this subsection describing darkroom fog;

(iv) paragraph (4)(B) of this subsection describing screen-film contact;

(v) paragraph (4)(C) of this subsection describing compression device performance;

(vi) paragraph (5)(A) of this subsection describing AEC;

(vii) paragraph (5)(C) of this subsection describing focal spot condition;

(viii) paragraph (5)(E) of this subsection describing reproducibility;

(ix) paragraph (5)(F) of this subsection describing dosimetry;

(x) paragraph (7) of this subsection describing quality control tests of other modalities; and

(xi) paragraph (8) of this subsection describing quality control tests for mobile mammography machines.

(C) Test results that are outside of the action limits shall be corrected as follows.

(i) In subparagraph (B)(i) or (iii) of this paragraph, corrective actions shall be taken before any mammography films are processed.

(ii) In subparagraph (B)(ii) or (iv)-(xi) of this paragraph, corrective actions shall be taken before any mammography examinations are performed.

(iii) In all other tests described in subsection (1) of this section, corrective actions shall be performed within 30 days of the test date.

(D) Documentation of the tests and the corrective actions described in subparagraphs (A)-(C) of this paragraph shall be maintained in accordance with subsection (nn)(3) of this section.

(10) Surveys. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist.

(A) At a minimum, this survey shall include the following:

(i) performance of tests to ensure that the facility meets the quality assurance requirements of the weekly phantom image quality test described in paragraph (2) of this subsection, the annual tests described in paragraph (5) of this subsection, and if applicable, paragraphs (7) and (8) of this subsection; and

(ii) evaluation of the adequacy of the results of all tests conducted by the facility as well as written documentation of any corrective actions taken and their results in accordance with paragraphs (1)-(4) of this subsection, and, if applicable, paragraphs (7) and (8) of this subsection.

(B) The medical physicist shall provide a written survey report to the facility within 30 days of the date of the survey. The report shall include a summary of the tests performed by the medical physicist in clause (i) of this subparagraph and the review of the tests performed by the facility in clause (ii) of this subparagraph. The report shall also contain recommendations for any required corrective actions.

(C) If deficiencies are noted that involve any of the items listed in paragraph (9)(B)(ii) and (vi)-(ix) of this subsection and, if applicable, paragraph (9)(x) and (xi) of this subsection, a preliminary oral or written report of the deficiencies shall be given to the facility within 72 hours of the survey.

(D) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.

(E) The survey report shall be maintained by the registrant in accordance with subsection (nn)(3) of this section.

(11) Mammography equipment evaluations. Additional evaluations of mammography machines or image processors shall be conducted whenever a new mammography machine or processor is installed, a mammography machine or processor is disassembled and reassembled at the same or a new location, major components of mammography machine are changed or repaired, or a processor is repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in subsections (g) and (l) of this section.

(A) All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing.

(B) The mammography equipment evaluation and dosimetry shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(12) Facility cleanliness. The registrant shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness and shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(13) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography machine shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6.0% (95% confidence level) in the mammography energy range.

(14) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

(A) comply with all applicable federal, state, and local regulations pertaining to infection control; and

(B) comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(C) if adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

(m) Quality assurance - mammography medical outcomes audit. Each registrant shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings.

(1) General requirements. Each registrant shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be complete within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months. These shall be maintained in accordance with subsection (nn)(3) of this section.

(3) Reviewing interpreting physician. Each lead interpreting physician or an interpreting physician designated by the lead interpreting physician shall review the medical outcomes audit data at least once every 12 months. This individual shall analyze the results of the audit and shall be responsible for the following:

- (A) recording the dates of the audit period(s);
- (B) documenting the results;
- (C) notifying other interpreting physicians of their results and the registrant's aggregate results; and
- (D) documenting any follow up actions and the nature of the follow up.

(n) Mammographic procedure and techniques for mammography of patients with breast implants. Each registrant shall have a procedure to inquire whether or not the patient has breast implants prior to the mammographic exam. Except where contraindicated, or unless modified by a physician's directions, patients with breast implants shall have mammographic views to maximize the visualization of breast tissue.

(o) Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

(p) Medical research. Any research using radiation producing devices on humans must be approved by an IRB as required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The IRB must include at least one licensed physician to direct any use of radiation in accordance with §289.231(b) of this title.

(q) Requirements for mammography systems used exclusively for invasive interventions for localizations or biopsy procedures. Mammography systems used exclusively for invasive interventions for localizations or biopsy procedures, including mobile services, are exempt from this section, except for the following:

(1) purpose and scope in accordance with subsections (a) and (b) of this section;

(2) the applicable definitions in subsection (c) of this section;

(3) prohibitions in accordance with subsection (d)(2) and (3) of this section;

(4) exemptions in accordance with subsection (e)(5) and (6) of this section;

(5) personnel operating equipment used exclusively for invasive interventions for localizations or biopsy procedures shall have a current certification as a medical radiologic technologist under the Medical Radiologic Technologist Certification Act, Texas Occupational Code, Chapter 601.

(A) Each medical radiologic technologist shall maintain qualifications by meeting the following requirements:

(i) participating in education programs by completing at least 6 CEUs on invasive interventions for localizations or biopsy procedures. The continuing education shall be completed in accordance with subsection (f)(2)(C)(i) of this section; and

(ii) performing a minimum of 24 mammographic biopsy examinations that shall be completed in accordance with subsection (f)(2)(C)(ii) of this section;

(B) If the medical radiologic technologist is an individual who meets the continuing education and experience requirements of subsection (f)(2) of this section, the accumulated CEUs and experience will satisfy the requirements of subparagraph (A) of this paragraph;

(6) medical physicists performing the tests in paragraph (9) of this subsection shall meet the personnel requirements in subsection (f)(3) of this section.

(7) equipment standards in accordance with subsection (g)(6) and (9) of this section;

(8) having a written quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility, including corrective actions to be taken if images are of poor quality;

(9) having a medical physicist perform an annual survey of AEC, kVp, focal spot condition, HVL, and dosimetry tests in accordance with subsection(l)(5)(A)-(D) and (F) of this section. The medical physicist shall provide a preliminary oral or written report of deficiencies within 72 hours of the survey if they involve AEC, focal spot, or dosimetry. The medical physicist shall prepare a written report for the facility within 30 days of the date of the survey to include the following:

(A) a summary of the tests in subsection (l)(5)(A)-(D) and (F) of this section with recommendations for corrective actions; and

(B) date and signature of the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey.

(10) correction of the deficiencies indicated in the test results in accordance with subsection (l)(9)(B)(vi), (vii), and (ix) of this section before any further examinations are performed;

(11) maintaining applicable records in subsection (r)(1)-(3);

(12) operating and safety procedures in accordance with subsection (s)(1) of this section;

§289.230(q)(13)

(13) occupational dose limits in accordance with subsection (s)(2) of this section;

(14) technique chart in accordance with subsection (s)(3) of this section;

(15) receipt, transfer, disposal, calibration, and maintenance records in accordance with subsection (s)(4) and (7) of this section;

(16) viewing system in accordance with subsection (s)(5) of this section;

(17) exposure of individuals other than the patient in accordance with subsection (s)(6) of this section;

(18) certification requirements, except for FDA accreditation, in accordance with subsection (t) of this section;

(19) issuance of certification and specific terms and conditions of certification in accordance with subsections (u) and (v) of this section;

(20) responsibilities of a registrant in accordance with the applicable portions of subsection (w) of this section;

(21) expiration, termination, renewal, modification, revocation, and reciprocity of certification in accordance with subsections (x)-(bb) of this section;

(22) inspections in accordance with subsection (cc) of this section, except for subsection (cc)(1) of this section;

(23) time requirements for record keeping in accordance with the applicable portions of subsection (nn)(3) of this section; and

(24) operating and safety procedures in accordance with the applicable portions of subsection (nn)(4) of this section.

(r) Record requirements. Records required by this section shall be maintained for inspection by the agency in accordance with subsection (nn)(3) of this section. Records may be maintained electronically in accordance with §289.231(ff)(3) of this title.

(1) Records for mammography machines authorized for mobile services.

§289.230(r)(1)(A)

(A) Copies of the following shall be kept with mammography machines authorized for mobile services:

(i) operating and safety procedures in accordance with subsection (r)(1) of this section;

(ii) medical radiologic technologists' credentials;

(iii) current quality control records for at least the last 90 calendar days for on-board processors in accordance with subsection (l)(1) of this section;

(iv) current §289.203 of this title, §289.226 of this title, §289.230 of this title, and §289.231 of this title;

(v) copy of certification of mammography system;

(vi) certification of inspection or notice of failure from last inspection, if applicable; and

(vii) copy of mammography facility accreditation.

(B) Copies of all other records required by this section shall be maintained at a specified location.

(2) Records required at authorized use locations. Copies of the following shall be kept at each authorized use location.

(A) operating and safety procedures in accordance with subsection (s)(1) of this section;

(B) quality assurance program in accordance with subsections (k), (l), and (m) of this section;

(C) credentials for interpreting physicians operating at that location in accordance with subsection (f)(1) of this section;

(D) credentials for medical radiologic technologists operating at that location in accordance with subsection (f)(2) of this section;

(E) credentials for medical physicists operating at that location in accordance with subsection (f)(3) of this section;

§289.230(r)(2)(F)

(F) quality control records in accordance with subsection (k)(2) of this section;

(G) continuing education and experience records for interpreting physicians, medical radiologic technologists, and medical physicists operating at that location in accordance with subsection (f)(1)(C), (2)(C), and (3)(C) of this section;

(H) current physicist annual survey of the mammography system;

(I) current §§289.203 of this title, 289.204 of this title, 289.205 of this title, §289.226 of this title, §289.230 of this title, and §289.231 of this title;

(J) copy of certification of mammography system;

(K) certification of inspection or notification of failure, if applicable;

(L) records of receipts, transfers, and disposal in accordance with subsection (s)(4) of this section;

(M) calibration, maintenance, and modification records in accordance with subsection (s)(7) of this section; and

(N) copy of mammography facility accreditation.

(s) Other operating procedures.

(1) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures that shall be made available to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. These procedures shall include, but are not limited to, the items in subsection (nn)(4) of this section.

(2) Occupational dose limits and personnel monitoring. Except as otherwise exempted, all individuals who are associated with the operation of a radiation machine are subject to the occupational dose requirements of §289.231(m) of this title and the personnel monitoring requirements of §289.231(n) and (q) of this title.

(3) Technique Chart. A chart or manual shall be provided or electronically displayed in the vicinity of the control panel of each machine that specifies technique factors to be utilized versus patient's anatomical size. The technique chart shall be used by all operators.

(4) Receipt, transfer, and disposal of mammography machines. Each registrant shall maintain records showing the receipt, transfer, and disposal of mammographic machines. These records shall include the date of receipt, transfer, or disposal, the name and signature of the individual making the record, and the manufacturer's model and serial number from the control panel of the mammographic machine. Records shall be maintained in accordance with subsection (nn)(3) for inspection by the agency.

(5) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit the operator to continuously observe the patient during irradiation. The operator shall be able to maintain verbal, visual, and aural contact with the patient.

(6) Exposure of individuals other than the patient. Only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiation exposure.

(7) Calibration, maintenance, and modifications. Each registrant shall maintain records showing calibrations, maintenance, and modifications performed on each mammographic machine. These records shall include the date of the calibration, maintenance, or modification performed, the name of the individual making the record, and the manufacturer's model and serial number of the control panel of the mammographic machine. These records shall be maintained in accordance with subsection (nn)(3) of this section.

(t) Certification requirements (state certification). In addition to the requirements of §289.226(f) and if applicable, (i) of this title, each applicant shall comply with the following.

(1) Each person having a mammographic x-ray machine shall apply for and receive certification for the mammography system from the agency before beginning use of the mammographic x-ray machine on humans.

(2) An application for mammography certification shall be signed by a licensed physician. The signature of the applicant and the radiation safety officer (RSO) shall also be required.

(3) An applicant for certification must obtain a certification on each mammography system that is used by the applicant or the applicant's agent (for the purposes of the requirements of this paragraph, the word "used" refers to the entity other than the technologist that directs the application of radiation to humans). An application for mammography system certification may contain information on multiple mammography machines. Each mammography machine must be identified by referring to the machine's manufacturer, model number, and serial number of the control panel. The registrant shall maintain and provide proof of current accreditation and FDA certification status. If accreditation or FDA certification expires before the expiration of the certification of mammography systems, the registrant shall submit proof of renewed status to the agency.

(4) The applicant shall be qualified by reason of training and experience to use the mammography machines for the purpose requested in accordance with this chapter in such a manner as to minimize danger to public health and safety.

(5) Each applicant shall submit documentation of the following:

(A) personnel qualifications, including dates of licensure or certification, in accordance with subsection (f) of this section;

(B) **manufacturer**, model, and serial number of each mammographic machine control panel;

(C) evidence of the following by a physicist meeting the requirements of subsection (f)(3) of this section:

(i) that each machine meets the equipment standards in subsection (g) of this section; and

(ii) the average glandular dose for one craniocaudal-caudal view for each machine does not exceed the value in subsection (l)(5)(F) of this section; and

(D) self-referral program information in accordance with subsection (h) of this section, if the facility offers self-referral mammography.

(6) Applications shall be processed in accordance with the following time periods.

(A) The first period is the time from receipt of an application by the Division of Licensing, Registration and Standards to the date of issuance or denial of the certification or a written notice outlining why the application is incomplete or unacceptable. This time period is 60 days.

§289.230(t)(6)(B)

(B) The second period is the time from receipt of the last item necessary to complete the application to the date of issuance or denial of the certification. This time period is 30 days.

(C) These time periods are exclusive of any time period incident to hearings and post-hearing activities required by the Government Code, Chapters 2001 and 2002.

(7) Notwithstanding the provisions of §289.204 of this title, reimbursement of application fees may be granted in the following manner.

(A) In the event the application is not processed in the time periods as stated in paragraph (6) of this subsection, the applicant has the right to request of the director of the Radiation Control Program full reimbursement of all application fees paid in that particular application process. If the director does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(B) Good cause for exceeding the period established is considered to exist if:

(i) the number of applications for certification to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(ii) another public or private entity utilized in the application process caused the delay; or

(iii) other conditions existed giving good cause for exceeding the established periods.

(C) If the request for full reimbursement authorized by subparagraph (A) of this paragraph is denied, the applicant may then request a hearing by appeal to the Commissioner of Health for a resolution of the dispute. The appeal will be processed in accordance with Formal Hearing Procedures, Chapter 1, §§1.21-1.34 of this title (relating to the Texas Board of Health).

(u) Issuance of certification of mammography systems. Issuance of certification of mammography systems shall be in accordance with §289.226(n) of this title.

(v) Specific terms and conditions of certification of mammography systems. Specific terms and conditions of certification of mammography systems shall be in accordance with §289.226(l) of this title.

(w) Responsibilities of registrant.

(1) In addition to the requirements of §289.226(p)(4)-(7) of this title, a registrant shall notify the agency in writing prior to any changes that would render the information contained in the application or the certification of mammography systems inaccurate. These include but are not limited to the following:

- (A) name and mailing address;
- (B) street address where machine(s) will be used; and
- (C) mammography machines.

(2) Prior to employing the individuals listed in subparagraphs (A)-(E) of this paragraph, the registrant is required to verify and maintain copies of their qualifications. Registrants utilizing relief interpreting physicians or technologists from a temporary service do not need to notify the agency unless these personnel will be at the facility for a period exceeding four weeks. Documentation of qualifications of individuals listed in subparagraphs (A)-(E) of this paragraph and notification of a change in any of the following is required within 30 days of such change:

- (A) radiation safety officer;
- (B) lead interpreting physician;
- (C) interpreting physicians;
- (D) operators of equipment; or
- (E) licensed medical physicist.

(3) Prior to operating mammography equipment at an additional use location, the registrant shall submit an application to the agency for approval and receive an amendment to the certification of mammography systems.

(4) The following criteria applies to new, replacement, or loaner mammography machines and mammography machines used for clinical trial evaluations.

(A) All mammography machines shall have either current accreditation or have submitted an application to an accreditation body for review. If accreditation expires, mammograms shall cease to be performed until such time as the accreditation application is received by the accreditation body and approval is given. Mammography machines that are loaner machines as described in subparagraph (C) of this paragraph or machines involved in clinical trial evaluations as described in subparagraph (D) of this paragraph are exempt from accreditation requirements.

(B) A facility with an existing certification of mammography system may begin using a new or replacement machine before receiving an updated certification if the paperwork regarding the machine has been submitted to the agency with a licensed medical physicist's report in accordance with subsection (l)(10) of this section verifying compliance of the new machine with this section. The physicist's report is required prior to using the machine on patients.

(C) Loaner mammography machines may be used on patients for 60 days without adding the mammography machine to the certification. A licensed medical physicist's report verifying compliance of the loaner mammography machine with this section shall be completed prior to use on patients. The results of the survey must be submitted to the agency with a cover letter indicating period of use. If the use period will exceed 60 days, the facility shall add the mammography machine to their certification and a fee will be assessed.

(D) Mammography machines involved in clinical trial evaluations may be used on patients for 60 days without adding the mammography machine to an existing certification. A licensed medical physicist's report verifying compliance of the unit with the manufacturer's specifications shall be completed prior to use on patients. If the use period will exceed 60 days, the facility shall add the machine to their certification and a fee will be assessed.

(E) No fees will be assessed for loaner mammography machines or evaluation periods of 60 days or less.

(F) Loaner mammography machines or mammography machines involved in clinical trial evaluations are exempt from the inspection requirement in subsection (cc)(1) of this section.

(5) Records of training and experience and all other records required by this section shall be maintained for review in accordance with subsection (nn)(3) of this section.

(x) Expiration of certification of mammography systems.

(1) Except as provided by subsection (z) of this section, each certification of mammography systems expires at the end of the day in the month and year stated on the certificate of registration on the expiration date specified. Expiration of the certification of mammography systems does not relieve the registrant of the requirements of this chapter.

(2) If a registrant does not submit an application for renewal of the certification of mammography systems under subsection (z) of this section, as applicable, the registrant shall on or before the expiration date specified in the certification of mammography systems:

(A) terminate use of all mammography machines;

(B) submit a record of the disposition of the mammography machines and film storage location of mammography patient's films; and

(C) pay any outstanding fees in accordance with §289.204 of this title.

(y) Termination of certification of mammography systems. When a registrant decides to terminate all activities involving mammography machines authorized under the certification of mammography systems, the registrant shall:

(1) notify the agency immediately;

(2) request termination of the certification of mammography systems in writing;

(3) submit a record of the disposition of the mammography machines;

(4) pay any outstanding fees in accordance with §289.204 of this title; and

(5) notify the agency of the film storage location of mammography patient's films.

(z) Renewal of certification of mammography systems.

(1) Application for renewal of certification shall be filed in accordance with this subsection and §289.226(e)(1)-(5) of this title.

§289.230(x)(2)

(2) If a registrant files an application in proper form at least 30 days before the existing certification expires, such existing certification shall not expire until the application status has been determined by the agency.

(3) A certification for a mammographic system is valid for three years from the date of issuance unless the certification of the facility is revoked prior to such deadlines. This is effective for certificates issued after September 1, 1997.

(A) If a registrant fails to renew the certification by the required date, the registrant may renew the certification on payment of the annual fee and a late fee. If the certification is not renewed before the 181st day after the date on which the certification expired, the registrant must apply for an original certification under this section.

(B) A mammography system may not be used after the expiration date of the certification unless the holder of the expired certification has made a timely and sufficient application for renewal of the certificate as provided in this subsection and §289.226(e)(1)-(5) of this title.

(aa) Modification and revocation of certification of mammography systems. Modification and revocation of certification of mammography systems shall be in accordance with §289.226(u) of this title.

(bb) Reciprocal recognition of out-of-state certificates of registration. Mammography machines will not be granted reciprocal recognition and must comply with the requirements of this section.

(cc) Inspections. In addition to the requirements of §289.231(kk) of this title, the following applies to inspections of mammography systems.

(1) The agency shall inspect each mammography system that receives a certification in accordance with this chapter not later than the 60th day after the date the certification is issued.

(2) The agency shall inspect, at least once annually, each mammography system that receives a certification.

(3) To protect the public health, the agency may conduct more frequent inspections than required by this subsection.

(4) The agency shall make reasonable attempts to coordinate inspections in this section with other inspections required in accordance with this chapter for the facility where the mammography system is used.

(5) After each satisfactory inspection, the agency shall issue a certificate of inspection for each mammography system inspected. The certificate of inspection shall be posted at a conspicuous place on or near the place where the mammography system is used. The certificate of inspection shall include the following:

(A) specific identification of the mammography system inspected;

(B) the name and address of the facility where the mammography system was used at the time of the inspection; and

(C) the date of the inspection.

(6) Any severity level I violation involving a mammography system, found by the agency, in accordance with §289.205 of this title, constitutes grounds for posting notice of failure of the mammography system to satisfy agency requirements.

(A) Notification of such failure shall be posted:

(i) on the mammography x-ray machine at a conspicuous place if the violation is machine-related; or

(ii) near the place where the mammography system practices if the violation is personnel-related; and

(iii) in a sufficient number of places to permit the patient to observe the notice.

(B) The notice of failure shall remain posted until the facility is authorized to remove it by the agency. A facility may post documentation of corrections of the violations submitted to the agency along with the notice of failure until approval to remove the notice of failure is received from the agency.

(7) The agency shall require registrants who receive a severity level I violation to notify patients on whom the facility performed a mammogram during the 30 days preceding the date of the inspection that revealed the failure. The facility shall:

(A) inform the patient that the mammography system failed to satisfy the agency's certification standards;

(B) recommend that the patient have another mammogram performed at a facility with a certified mammography system; and

(C) list the three facilities closest to the original testing facility that have a certified mammography system.

(8) In addition to the requirements of paragraph (7) of this subsection, the agency may require a facility to notify a patient of any other failure of the facility's mammography system to meet the agency's certification standards.

(9) The patient notification shall include the following:

(A) explanation of the mammography system failure to the patient; and

(B) the potential consequences to the mammography patient.

(10) The registrant shall maintain a record of the mammography patients notified in accordance with paragraphs (7) and (8) of this subsection for inspection by the agency. The records shall include the name and address of each mammography patient notified, date of notification, and a copy of the text sent to the individual.

(dd) Accreditation of mammography facilities.

(1) All mammography facilities shall be accredited by an authorized FDA accreditation body. All facilities applying for and receiving accreditation through the agency shall comply with §289.231 (f)-(h), (j), (k), and (aa) of this title, §289.203 of this title, §289.205 of this title, and subsections (f) and (g), (i)-(o), (s), (w), (cc), (ee), (hh) and (nn)(1)-(4) of this section.

(2) In order to be accredited by the agency, the applicant shall submit an application for accreditation on forms and in accordance with accompanying instructions prescribed by the agency.

(A) Each application shall be signed by a licensed physician.

(B) The agency may at any time after the filing of the original application, require further statements in order to enable the agency to determine whether the accreditation document should be issued, denied, modified, or revoked.

(C) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with §289.231(aa) of this title.

§289.230(dd)(2)(D)

(D) Each application for accreditation shall be accompanied by the fee prescribed in subsection (ee) of this section.

(E) Each applicant shall submit documentation of the following:

(i) personnel qualifications, training, and experience in accordance with subsection (f) of this section;

(ii) manufacturer model and serial number of each mammographic machine control panel; and

(iii) evidence that a medical physicist performed a survey and/or a mammography equipment evaluation in accordance with subsection (l)(10) and (11) of this section within the following time frames:

(I) no earlier than six months before the date of the accreditation application for new facilities seeking accreditation;

(II) no earlier than twelve months before the date of the application for accreditation for facilities changing accreditation to one issued by this agency; or

(III) no earlier than 12 months before the date of the application for renewal of accreditation for facilities accredited by this agency.

(F) Upon notification by the agency, each applicant shall directly submit clinical and phantom images to the image review board in accordance with their procedures.

(ee) Fees for accreditation of mammography facilities.

(1) Each application for accreditation of a mammography facility shall be accompanied by a nonrefundable fee. No application will be accepted for filing or processed prior to payment of the full amount specified in paragraph (3) of this subsection.

(2) Fee payments shall be in cash or by check or money order made payable to the Texas Department of Health. The payments may be mailed or made by personal delivery to the Bureau of Radiation Control, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3189.

(3) Fees for accreditation of mammography facilities are as follows.

§289.230(ee)(3)(A)

(A) The accreditation fee for the first mammography machine is \$850.

(B) The accreditation fee for each additional mammography machine is \$460.

(C) The fee for re-evaluation of clinical images due to failure during the accreditation process is \$250 per mammography machine.

(D) The fee for re-evaluation of phantom images due to failure during the accreditation process is \$200 per machine.

(E) The fee for an additional mammography review will be based on the number of clinical image sets reviewed and the type of review.

(F) The fee for reinstatement of a mammography machine is \$580.

(G) The fee for replacement of thermoluminescent dosimeters (TLD) is \$70.

(H) Each facility for which a targeted clinical image review is required will be charged for actual expenses to the agency arising from the visit.

(I) Each facility for which an on-site visit due to three denials of accreditation is required will be charged for actual expenses to the agency arising from such visit.

(J) Payment of the fees in subparagraphs (H) and (I) of this paragraph shall be made within 60 days following the date of invoice.

(ff) Issuance of accreditation of a mammography facility. An accreditation document will be issued when the mammography facility meets the requirements of subsections (dd) and (ee) of this section and becomes accredited by the agency. In order for an accreditation to be issued, the agency must be notified by the image review board that the applicant met the criteria for clinical images, phantom images, and dose evaluation.

(gg) Specific terms and conditions of accreditation of mammography facilities.

(1) Each accreditation document issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable requirements and orders of the agency.

(2) No accreditation document issued by the agency under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person.

(hh) Responsibilities of an accredited facility. A facility shall notify the agency of any changes that would render the information contained in the application inaccurate.

(ii) Expiration and renewal of accreditation of mammography facilities.

(1) The accreditation shall expire on the date specified on the accreditation document.

(2) Application for renewal of accreditation shall be filed in accordance with subsections (dd) and (ee) of this section.

(3) A mammography facility filing an application for renewal in accordance with (dd) and (ee) at least four months before the existing accreditation expires may continue to perform mammography until the review process is complete and the accreditation status has been determined by the agency.

(4) A mammography facility filing an application for renewal in accordance with (dd) and (ee) less than four months before the existing accreditation expires:

(A) may continue to perform mammography until the expiration date of the accreditation; or

(B) if the facility receives written authorization from the agency, may continue to perform mammography until the review process is complete and the accreditation status has been determined by the agency.

(5) Accreditation for a mammographic facility is valid for three years from the date of issuance, unless accreditation of the facility is revoked prior to such deadline.

(6) Issuance of renewal of accreditation shall be in accordance with subsection (ff) of this section.

(jj) Denial or abandonment of an application for accreditation of mammography facilities.

(1) Denial of an application.

(A) Any application for accreditation may be denied by the agency when the applicant fails to meet established criteria for accreditation in accordance with subsection (dd) of this section.

(B) Before the agency denies an application for accreditation, the agency shall give notice of the intent to deny, and the facts warranting the denial, and shall afford the applicant an opportunity for a hearing in accordance with §289.205(h) of this title. If no request for a hearing is received by the director of the Radiation Control Program within 30 days of personal service or the date of mailing, the agency may proceed to deny. The applicant shall have the burden of proof showing cause why the application should not be denied.

(2) Abandonment of an application. Agency action on an application will be abandoned due to lack of response by the applicant to a request for information by the agency. Abandonment of such actions does not provide an opportunity for a hearing; however, the applicant retains the right to resubmit the application and pay a reinstatement fee at any time.

(kk) Revocation and suspension of accreditation of mammography facilities.

(1) Revocation of accreditation of mammography facilities shall be in accordance with §289.205 of this title.

(2) Suspension of accreditation of mammography facilities.

(A) An accreditation of a mammography facility may be suspended for any of the following reasons:

(i) any material false statement in the application or any statement of fact required under provision of the Act;

(ii) conditions revealed by such application or statement of fact or any report, record, inspection, or other means that would warrant the agency to refuse to grant an accreditation of mammography facility on an original application; or

(iii) failure to observe any of the terms and conditions of the Act, this chapter, or order of the agency.

(B) Before the agency suspends an accreditation of a mammography facility, the agency shall give notice by personal service or by certified mail, addressed to the last known address, of the facts or conduct alleged to warrant the revocation by complaint, and order the accredited mammography facility to show cause why the mammography facility accreditation should not be suspended. The accredited mammography facility shall be given an opportunity to request a hearing on the matter no later than 30 days after receipt of the notice.

(C) Any accredited mammography facility against whom the agency contemplates an action described in subparagraph (A) of this paragraph may request a hearing by writing the director within 30 days of service or date of mailing.

(j) The written request for a hearing must contain the following:

(I) statement requesting a hearing;

(II) name, address, and identification number of the accredited mammography facility against whom the action is being taken.

(ii) Failure to submit a written request for a hearing within 30 days will render the agency action final.

(D) If the agency suspends the accreditation of a mammography facility in accordance with subparagraph (A) of this paragraph, the suspension shall remain in effect until the agency determines the following:

(j) that allegations of violations or misconduct were not substantiated;

(ii) that violations of required standards have been corrected to the agency's satisfaction; or

(iii) the facility's accreditation is revoked in accordance with §289.205 of this title.

(II) On-site facility visit, targeted clinical image review, and random film checks. Each accredited facility shall:

(1) afford the agency, at all reasonable times, opportunity to audit the facility where mammography equipment or associated equipment is used or stored;

(2) make available to the agency for inspection, upon reasonable notice, records maintained in accordance with this chapter; or

(3) upon request by the agency, make clinical images available to the image review board for a targeted clinical review or random clinical images review.

(mm) Complaints. Each facility with accreditation from the agency shall do the following:

(1) establish a written procedure for collecting and resolving consumer complaints;

(2) maintain a record of each serious complaint received by the facility in accordance with subsection (nn)(3) of this section; and

(3) report unresolved serious complaints to the agency within 30 days of receiving the complaint.

(nn) Appendices.

(1) Subjects to be included in mammography training for medical radiologic technologists shall include, but not be limited to, the following:

(A) anatomy and physiology of the female breast that shall include:

(i) mammary glands;

(ii) external anatomy;

(iii) retromammary space;

(iv) central portion;

(v) Cooper's ligament;

(vi) vessels, nerves, lymphatics; and

(vii) breast tissue:

(I) fibro-glandular;

(II) fibro-fatty;

(III) fatty; and

(IV) lactating;

(B) mammography positioning that shall include actual positioning of patients and/or models as follows:

- (i) craniocaudal;
 - (ii) mediolateral oblique;
 - (iii) supplemental;
 - (iv) magnification;
 - (v) errors in positioning;
 - (vi) postoperative breast and the augmented breast;
 - (vii) breast localization and specimen radiography; and
 - (viii) use of compression;
- (C) technical factors;
- (D) film evaluation and critique;
- (E) pathology; and
- (F) quality assurance program.

(2) Subjects to be included in mammography training for interpreting physicians shall include, but not be limited to, the following:

- mammography;
- (A) radiation physics, including radiation physics specific to mammography;
 - (B) radiation effects;
 - (C) radiation protection; and
 - (D) interpretation of mammograms. This shall be under the direct supervision of a physician who meets the requirements of subsection (f)(1) of this section.

(3) Time requirements for record keeping. Time requirements for record keeping shall be in accordance with the following chart.

<u>Specific Subsection</u>	<u>Name of Record</u>	<u>Time Interval for Record Keeping</u>
(k)(2)	Quality Assurance (QA) Records	2 years
	Films associated with QA	1 year
(f)(1)(A)	Interpreting Physician Qualifications	Until termination of certification or 2 years after physician leaves facility
(f)(1)(C)	Interpreting Physician Continuing Education and Experience	6 years
(f)(2)(A)	Medical Radiologic Technologist Qualifications	Until termination of certification or 2 years after technologist leaves facility
(f)(2)(C)	Medical Radiologic Technologist Continuing Education and Experience	6 years
(f)(3)(A)	Medical Physicist Qualifications	Until physicist is no longer associated with facility
(f)(3)(C)	Medical Physicist Continuing Education and Experience	6 years
(g)(14)	FDA Variances	Until termination of certification or equipment is replaced
(l)(10)	Physicist Mammography Survey	7 years
(l)(11)	Physicist Mammography Equipment Evaluation	2 years
(m)(2)	Medical Outcomes Audit	2 years
(s)(4)	Records of Receipts, Transfer, and Disposal	Until termination of certification
(s)(7)	Records of Calibration, Maintenance, and Modifications Performed on Mammography Machines	2 years

<u>Specific Subsection</u>	<u>Name of Record</u>	<u>Time Interval for Record Keeping</u>
(cc)(5)	Certification of Inspection	Until termination of certification
(cc)(6)	Notice of Failure	Until termination of certification
(cc)(10)	Patient Notification	Until termination of certification
(nn)(2)	Complaints	2 years

(4) Operating and safety procedures. The registrant's operating and safety procedures shall include, but are not limited to, the following procedures as applicable:

(A) ordering x-ray exams in accordance with §289.231(b) of this title;

(B) occupational dose requirements in accordance with §289.231(m) of this title;

(C) posting of a radiation area in accordance with §289.231(x) and (y) of this title;

(D) personnel monitoring requirements in accordance with §289.231(n) and (q) of this title;

(E) posting notices to workers in accordance with §289.203(b) of this title;

(F) instructions to workers in accordance with §289.203(c) of this title;

(G) notifications and reports to individuals in accordance with §289.203(d) of this title;

(H) credentialing requirements for lead interpreting physicians, interpreting physicians, medical radiologic technologists, and medical physicists in accordance with subsection (f) of this section;

(I) self-referral mammography in accordance with subsection (h) of this section;

(J) retention of clinical images in accordance with subsection (i)(4) of this section;

(K) quality assurance program in accordance with subsections (k)-(m) of this section;

(L) image quality and corrective action for images of poor quality in accordance with subsection (k)(1)(B)(i) of this section;

(M) repeat analysis in accordance with subsection (l)(3)(B) of this section;

(N) procedures and techniques for mammography patients with breast implants;

(O) use of a technique chart in accordance with subsection (s)(3) of this section;

(P) exposure of individuals other than the patient in accordance with subsection (s)(6) of this section; and

(Q) procedure to handle complaints in accordance with subsection (mm) of this section.

(5) Phantom image scoring protocol. Each of the following object groups are to be scored separately. In order to receive a passing score on the phantom image, all three test object groups must pass. A failure in any one of the areas results in a phantom failure.

(A) Fibers. A score of 4.0 for fibers is required to meet the evaluation criteria. The diameter size of fibers are 1.56 mm, 1.12 mm, 0.89 mm, 0.75 mm, 0.54 mm, and 0.40 mm. Score the fibers as follows.

(i) Begin with the largest fiber and move down in size, adding one point for each full fiber until a score of zero or one half is given. Stop counting at the first point where you lose visibility of objects.

(ii) If the entire length of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one.

(iii) If at least half, but not all, of the fiber can be seen and its location and orientation are correct, that fiber receives a score of one half.

(iv) If less than one half of a fiber can be seen or if the location or orientation are incorrect, that fiber receives a score of zero.

(v) After determining the last fiber to be counted, look at the overall background for artifacts. If there are background objects that are fiber-like in appearance and are of equal or greater brightness than the last visible half or full fiber counted, subtract the last half or full fiber scored.

(B) Speck groups. A score of 3.0 for speck groups is required to meet the evaluation criteria. Diameter sizes of speck groups are 0.54 mm, 0.40 mm, 0.32 mm, 0.24 mm, and 0.16 mm. There are six specks per group. Score the speck groups as follows.

(i) Begin with the largest speck group and move down in size adding one point for each full speck group until a score of one half or zero is given, then stop.

(ii) If at least four of the specks in any group are visualized, the speck group is scored as one.

(iii) If two or three specks in a group are visualized, the score for the group is one half.

(iv) If one speck or no specks from a group are visualized, the score is zero.

(v) After determining the last speck group to receive a full or one-half point, look at the overall background for artifacts. If there are speck-like artifacts within the insert region of the phantom that are of equal or greater brightness than individual specks counted in the last visible half or full speck group counted, subtract the artifact speck from the observed specks, one by one. Repeat the scoring of the last visible speck group after these deductions.

(C) Masses. A score of 3.0 is required to meet the evaluation criteria. Diameter sizes of masses are 2.00 mm, 1.00 mm, 0.75 mm, 0.50 mm, and 0.25 mm. Score the masses as follows.

(i) Begin with the largest mass and add one point for each full mass observed until a score of one half or zero is assigned.

(ii) Score one for each mass that appears as a minus density object in the correct location that can be seen clearly enough to observe round, circumscribed borders.

(iii) Score one half if the mass is clearly present in the correct location, but the borders are not visualized as circular.

(iv) After determining the last full or half mass to be counted, look at the overall background for artifacts. If there are background objects that are mass-like in appearance and are of equal or greater visibility than the last visible mass, subtract the last full or half point assigned from the original score.

TEXAS REGISTER FORMAT EXPLANATION

The following example is the outline format used for all agency rules. This explanation will help you locate the different references stated throughout the rule:

§289.xxx = sections are the titles	289.252	Licensing of Radioactive Material
(a) = subsections are the lowercase letters in parenthesis	(a)	Appendices.
(1) = paragraphs are the numbers in parenthesis	(1)	Criteria relating to use of financial tests and parent company...
(A) = subparagraphs are the UPPERCASE letters in parenthesis	(A)	Financial test.
(j) = clauses are the <i>italicized</i> lowercase roman numerals in parenthesis	(j)	To pass the financial test, the parent company...
(J) = subclauses are the <i>italicized</i> UPPERCASE roman numerals in parenthesis	(J)	The parent company shall have:
(-a-) = items are the lowercase letters with hyphens in parenthesis	(-a-)	two of the following...:
(-1-) = subitems are the numbers with hyphens in parenthesis	(-1-)	a ratio of total liabilities to...;

FOR EXAMPLE:

When the rule states "paragraph (1) of this subsection", the rule is referring to paragraph "(1)" within subsection "(a)."

When the rule states "subsection (d) of this section", the rule is referring to subsection "(d)" within the section, for example, §289.252.

WHERE CAN THE FORMS REFERENCED
WITHIN THE RULE BE FOUND?

PLEASE SEE THE BUREAU OF RADIATION CONTROL WEB SITE AT:

WWW.TDH.STATE.TX.US/ECH/RAD/PAGES/BRC.HTM FOR ANY FORMS THAT ARE REFERENCED WITHIN THE RULE TEXT BUT ARE NOT INCLUDED WITH THE RULE PACKET OR CALL (512) 834-6688 TO REQUEST A COPY(IES) OF THE FORM(S).